HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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Refer to: CFN 1122506

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

November 22, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Abdulla Abdulla, President
Virotech International, Incorporated
13 Taft Court
Rockville, Maryland 20850

Dear Dr. Abdulla:

During an inspection of your facility located at 13 Taft Court, Rockville, Maryland conducted by the Food and Drug Administration (FDA) from August 23 to 26, 1999, investigators determined that you manufacture and distribute for export Human Immunodeficiency Virus (HIV) 1/2 Gold Spot Test Kits and HIV 1/2 Rapid ELISA Assay Test Kits. These test kits are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The devices have been shipped in interstate commerce in violation of Section 301(a) of the Act since serious violations were documented that cause these devices to be adulterated within the meaning of Sections 501(f)(1)(B) and 501(h) and misbranded within the meaning of Section 502(o) of the Act.

Our inspection revealed that the devices are misbranded under Section 502(o) of the Act, in that the devices are manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510, are not included in a list required by Section 510(j), and a notice or other information respecting the device has not been provided to the FDA as required by Section 510(k).

Our inspection determined that the HIV 1/2 Gold Spot Test Kits and the HIV 1/2 Rapid ELISA Assay Test Kits are in domestic commerce as the kits are sold by your firm to a distributor in the United States. These devices, therefore, are adulterated under Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have an approved application for pre-market approval in effect pursuant to Section 515(a), or an approved application for an investigational device exemption under Section 520(g). The inspection further showed that the HIV test kits do not meet the requirements for either of the applicable export exemptions of the Act, Sections 801(e)(2) and 802. As a result, the products may not be legally exported.

These devices are also adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packaging, storage, or installation, are not in conformance with Current Good Manufacturing Practices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, Quality System Regulation for Medical Devices, as follows:

I - Quality Systems Regulation

- Failure to establish or maintain adequate Device Master Records.
- Failure to establish or maintain adequate Device History Records.
- Failure to conduct design validation on finished HIV test kits, in that a 1-year expiration date is listed for the kits and no stability data is documented.
- Failure to ensure the shipping process meets the storage specifications required for components, in that the HIV test kits are to be stored at 2-8 degrees C.
- Failure to identify suitable means for production acceptance to indicate conforming or non-conforming product.
- Failure to follow standard operating procedures (SOPs), in that the number of finished devices released to final inventory is not documented as required by SOPs.
- Failure to assure that changes in SOPs are reviewed and approved.

II – Distribution Issues

Your firm does not demonstrate due diligence, as there is no documented evidence that the distributor to whom you sell your devices is aware that the devices are unapproved. Furthermore, there is documentation to show that, while your firm labels your devices "FOR RESEARCH USE ONLY," you are aware that these devices are being labeled by the distributor for "In Vitro Diagnostic Use" and exported for that purpose.

III – Labeling Issues

Examples of Virotech product insert labeling, as well as the package and product insert labeling completed by the distributor, [redacted] were collected during the inspection. FDA's Center for Biologics Evaluation and Research and Center for Devices and Radiological Health have reviewed the labeling and have the following comments:

1. The HIV 1/2 Gold Spot Test Kits and HIV 1/2 Rapid ELISA Assay Test Kits' labeling, "FOR RESEARCH USE ONLY," is inadequate. The labeling should state "For Research Use Only. Not For Diagnostic Procedures." Test kits labeled "For Research Use Only" should not contain "Interpretation of Results."

2. While the HIV 1/2 Gold Spot Test Kit device is labeled "FOR RESEARCH USE ONLY," the same labeling also states that the kit "can be used as a screening test in hospitals, laboratories, medical clinics, and blood banks" and "It is intended to be used in emergency care situations when results are needed within minutes (e.g. emergency rooms, autopsy rooms, funeral homes, brothel houses, and ports of entry or in situations where ELISA is not practical or available)," indicating the kit is intended for in vitro diagnostic use.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA and promptly initiating permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so they may take this information into account when considering the award of contracts or when issuing certificates of export. Additionally, no pending applications for pre-market approval (PMAs) will be approved, and no pre-market notifications [510(k)s] will be found substantially equivalent for products manufactured at the facility in which the above GMP violations were found, until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including the timeframe within which the corrections will be completed. Corrective actions should also indicate the person responsible for effecting the correction, and include any supporting documentation indicating that correction has been achieved. Your response should include your intentions with regard to the HIV test kits that have been illegally shipped in domestic commerce. If corrections cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

Lee Bowers
Director, Baltimore District